IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: All Cases	

PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR RECONSIDERATION AND FOR CLARIFICATION

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INTRODUCTION

The Plaintiffs' Steering Committee ("PSC") on behalf of the plaintiffs identified in Exhibit A to the certain defendants' motion to dismiss, respectfully submits this memorandum of law in support of their motion for reconsideration of the Court's order dated November 9, 2015 (the "Order"), granting the motion filed by Defendants Actavis, Inc., Actavis Pharma, Inc., Actavis Laboratories UT, Inc., Watson Laboratories, Inc., and Anda, Inc. ("the Actavis Defendants") and Pfizer Inc. and Pharmacia & Upjohn Company LLC ("the Pfizer Defendants") to dismiss all claims in this multi-district litigation arising from the use of Depo-Testosterone and Testopel, each of which was approved pursuant to an abbreviated new drug application ("ANDA") and is now the reference listed drug ("RLD") for its category. (Together, the Pfizer Defendants and the Actavis Defendants are referred to as the "ANDA Defendants.") The Court found that Plaintiffs' claims pertaining to these drugs were preempted by federal law because, the Court found, the regulations promulgated by the federal Food & Drug Administration ("FDA") permitting drug manufacturers to make unilateral changes to their labels (the so-called "changes being effected," or CBE, regulations) do not apply to drugs that were approved pursuant to an ANDA. The Court also denied Plaintiffs request for discovery with respect to unilateral changes previously made to the labels for Depo-Testosterone and Testopel.

Plaintiffs seek reconsideration only with respect to the latter portion of the Order, denying Plaintiffs' request for discovery. Plaintiffs believe that, in denying this request, the Court may have misapprehended what Plaintiffs were arguing with respect to the record and the significance of the ANDA Defendants' previous unilateral changes to the labels for their ANDA drugs. Finding the question to be an issue of law, the Court held that "[a]dditional facts about whether the ANDA defendants have *attempted* to make such unilateral changes would not alter that legal conclusion." Order at 15 (emphasis added). Plaintiffs believe, however, that the issue is not whether the ANDA Defendants *attempted* to make unilateral changes to their labels, but rather whether they in fact successfully did

so. This distinction is especially important because, in finding Plaintiffs' claims preempted, the Court relied heavily on its finding about the FDA's likely interpretation of the CBE regulations in this situation, even though the FDA has never directly addressed this precise issue. In this context, the FDA's actions or pronouncements, if any, on actual unilateral changes made by the ANDA Defendants or their predecessors to the labels for these particular drugs would provide more direct evidence of the FDA's interpretation of its regulations than was (or is) otherwise available to the Court. Thus, while the Court found that the ANDA Defendants were precluded from making unilateral changes to the labels for Depo-Testosterone and Testopel, the FDA may have found precisely the opposite, that these defendants were entitled to make such changes. If they were, the ANDA Defendants' entire argument for federal preemption falls apart, for only if the FDA would prohibit such unilateral changes would the ANDA Defendants be unable to comply with both their federal law and their state-law duties. Moreover, any FDA action demonstrating approval of the use of the CBE regulations with respect to these specific products would provide evidence that, not only were the ANDA Defendants permitted to make unilateral changes to the labels for Depo-Testosterone and Testopel, *but they knew they were permitted to make such changes*. Rather than relying on a conjecture about how the FDA would react to a unilateral label change for these products, the ANDA Defendants may well have had specific knowledge of how the FDA in fact understood the operation of the CBE regulations in the context of an ANDA drug that is also an RLD.

Nor is Plaintiffs' request for discovery on this point based on mere speculation. Plaintiffs submitted evidence with their motion showing that the ANDA Defendants had in fact made unilateral changes to the labels for these drugs. Given that this occurred, the fate of these label changes, and, in particular, the FDA's position in permitting (or rejecting) such unilateral changes, is highly relevant to the Court's determination of whether the ANDA Defendants were in fact precluded from adding the warnings

Plaintiffs contend they should have added. Because Plaintiffs believe the Court may have misapprehended or overlooked the significance of the discovery they were seeking, Plaintiffs respectfully request that the Court reconsider its denial of discovery on this point.

In addition, Plaintiffs seek clarification of the scope of the Court's Order. Plaintiffs understand that the Order applies to all claims that relate to the warnings provided in the label or to the design of Defendants' products, all of which were approved by the FDA, and, by extension, to any claim grounded in a failure to disclose information not in the labels for the products at issue. None of the briefing, however, focused specifically on the Seventh Claim for Relief in the Master Complaint, which asserts a fraud claim based on affirmative misrepresentations made by all of the defendants outside the various labels and pertaining to off-label marketing. Specifically, Plaintiffs allege that defendants invented a fictitious disease or medical condition that they called "Low T" and, through affirmative misrepresentations in advertising materials and on the Internet, deceived Plaintiffs and their doctors into believing that the condition was real and that Plaintiffs suffered from it. *See* Third Amended Master Complaint ¶¶ 542-558. None of the arguments the ANDA Defendants made concerning preemption addressed such affirmative misrepresentations, as it should be clear that FDA approval of the labels for TRT products, including the indications and warnings applicable to the use of these products for hypogonadism, could not possibly have required the ANDA Defendants to invent a completely different condition and fraudulently to sell their products as a "cure" for this invented condition, nor do such claims arise from a contention that the ANDA Defendants ought to have changed the labels for their products, or redesigned the products, in any way. Neither the parties' papers nor the Court's opinion addressed specifically the applicability of preemption to claims unrelated to information in the label, which are not grounded in a contention that the ANDA Defendants ought to have made changes to their labels. The Court's Order appears to dismiss all claims asserted against

the ANDA Defendants, but the basis on which the Court's reasoning could be applied to the Seventh Claim for Relief is not spelled out. Accordingly, Plaintiffs seek clarification of the scope of the Order, as to whether the affirmative fraud claim is in fact included and, if so, on what basis.

PROCEDURAL HISTORY

On May 15, 2015, the ANDA Defendants filed their Motion to Dismiss and for Judgment on the Pleadings Pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(c) (D.E. 770). In their motion, Defendants argued that because Depo-Testosterone and Testopel were approved through abbreviated new drug applications, Plaintiffs' claims are preempted by the federal Food, Drug & Cosmetic Act ("FDCA").

The PSC filed its Memorandum in Opposition to the ANDA Defendants' motion on June 15, 2015, arguing that that the Plaintiffs' claims were not preempted because Depo-Testosterone and Testopel are "reference listed drugs" and that, with respect to such drugs, the ANDA Defendants are not prevented from making unilateral changes to their labels to comply with state tort law duties (D.E. 820). In support of that argument, Plaintiffs submitted evidence of at least two instances of unilateral label changes made by the ANDA Defendants with respect to the precise products at issue. The PSC argued in the alternative that the Court should permit Plaintiffs to take discovery with respect to these and other unilateral label changes the ANDA Defendants have made with respect to Depo-Testosterone and Testopel, as well as the FDA's response to them.

The ANDA Defendants filed their reply memorandum on June 29, 2015 (D.E. 858). Defendants argued that certain statements made in FDA materials in 2013 foreclosed any argument against preemption in the context of ANDA holders, even with respect to RLDs, and that further discovery was unwarranted.

On November 9, 2015, the Court issued its Order, granting the ANDA RLD Defendants' Motion to Dismiss and denying Plaintiffs' request for discovery (D.E. 1051). Plaintiffs now seek reconsideration of that portion of the Court's Order denying

Plaintiffs' request for discovery with respect to unilateral changes to the Depo-Testosterone and Testopel labels made through the CBE process, or in the alternative, seek entry of a partial final judgment pursuant to Rule 54(b).

LEGAL STANDARD

A motion for reconsideration performs a valuable, but limited function: "to correct manifest errors of law or fact." *Caisse Nationale De Credit Agricole v. CBI Indus., Inc.*, 90 F.3d 1264, 1269-70 (7th Cir. 1996).[1] A motion for reconsideration is proper when "the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *Bank of Waunakee v. Rochester Cheese Sales, Inc.*, 906 F.2d 1185, 1191 (7th Cir. 1990). In other words, it is properly granted when the court "overlooked or misunderstood something." *Hickory Farms, Inc. v. Snackmasters, Inc.*, 509 F. Supp. 2d 716, 719 (N.D. Ill. 2007); *see also Valero Energy Corp. v. U.S.*, No. 06-C-6730, 2008 WL 4104367 (N.D. Ill. Aug. 26, 2008) (Kennelly, J.) ("reconsideration of a ruling is appropriate . . . when the court has made a decision outside the adversarial issues the parties presented; the court has misunderstood the evidence or arguments; there has been an intervening change in the law; or when a party has newly discovered evidence unavailable when the matter was initially briefed."). Such a motion "essentially enables a district court to correct its own errors, sparing the parties and the appellate courts the burden of unnecessary appellate proceedings." *Russell v. Delco Remy Div. of Gen. Motors Corp.*, 51

[1] As this Court has recognized, a motion for reconsideration is not properly made under either Fed. R. Civ. P. 59 or Fed. R. Civ. P. 60, both of which apply only to final orders and judgments. *See Valero Energy Corp. v. U.S.*, No. 06-C-6730, 2008 WL 4104367 (N.D. Ill. Aug. 26, 2008) (Kennelly, J.); *see also Kapco Mfg. Co. v. C & O Enterprises, Inc.*, 773 F.2d 151, 154 (7th Cir. 1985). In *Valero*, this Court referred to such a motion as "what would commonly be called a motion for reconsideration," and Plaintiffs have accordingly styled their motion as such. *See also* Fed. R. Civ. P. 54(b) (providing that an order "may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities."

F.3d 746, 749 (7th Cir. 1995). "[T]he court must strike the proper balance between two competing imperatives: (1) finality; and (2) the need to render just decisions on the basis of all the facts." *Oto v. Metro. Life Ins. Co*, 224 F.3d 601, 606 (7th Cir. 2000). The decision to grant or deny the motion is entrusted to the district court's discretion. *See Andrews v. E.I. Du Pont De Nemours & Co.*, 447 F.3d 510, 515 (7th Cir. 2006).

ARGUMENT

I. THE COURT SHOULD RECONSIDER ITS NOVEMBER 9, 2015 ORDER AND PERMIT PLAINTIFFS TO TAKE DISCOVERY WITH RESPECT TO WHETHER THE FDA PERMITTED UNILATERAL CBE AMENDMENTS TO THE LABELS IN QUESTION BEFORE THE COURT RULES ON THE ANDA DEFENDANTS' MOTION TO DISMISS

As the Court recognized in its Order, the question whether Plaintiffs' claims arising from the ANDA reference-listed drugs, Depo-Testosterone and Testopel, are preempted turns on whether the ANDA Defendants are permitted to make unilateral changes to the labels for those drugs under the CBE regulations. Order at 6-7. In holding that the claims were preempted, this Court relied on two FDA Guidances suggesting that the CBE process is not available to ANDA-holders. *Id.* at 12-14. Neither Guidance addressed the precise question at issue here (that is, whether an ANDA-holder whose ANDA product is also a RLD may use the CBE process to make unilateral changes), but both Guidances contained language suggesting that, at least in ordinary circumstances, ANDA-holders may not make use of unilateral, CBE changes. Plaintiffs respectfully disagree with this Court's interpretation of the underlying regulations and the FDA Guidances, but recognize that this disagreement does not form a proper basis for a motion for reconsideration.

With respect to Plaintiffs' alternative request for discovery, which the Court also denied, Plaintiffs believe that reconsideration is appropriate because the Order strongly suggests that the Court misunderstood the argument Plaintiffs were making about discovery and/or misapprehended the nature of the evidence that Plaintiffs submitted in

support of their request for discovery. In support of their request for discovery, Plaintiffs submitted evidence of two unilateral, CBE changes made to the label for Depo-Testosterone in 1991 and 1996 (D.E. 819). Both changes were made with specific reference to FDA regulations that permit changes to be made *prior* to FDA approval of the changes – that is, changes that can be made unilaterally by the drug manufacturer without waiting for regulatory approval. *Id.*, *citing* 21 C.F.R. 314.70(c). Both changes were ultimately approved by the FDA. *Id.* Plaintiffs recognize that the record reflecting these changes, and how they were made, is sparse – but that is precisely the point. Plaintiffs seek discovery in order to establish (1) that these changes were in fact made to the Depo-Testosterone label prior to receipt of FDA approval; (2) that FDA agreed that the changes could be made in this manner, pursuant to the CBE regulations, and did not require prior approval; and (3) whether additional unilateral changes were made to the Depo-Testosterone label (or to the Testopel label), and if so, how many times such changes were made and whether the FDA at any time indicated that the CBE regulations permitting these unilateral changes were not the correct avenue for these ANDA-approved drugs.[2]

In rejecting Plaintiffs' request for discovery, the Court held that any attempts by the ANDA Defendants to change their labels unilaterally could have no bearing on whether they were legally entitled to make such changes. Order at 15. Plaintiffs respectfully suggest that the Court misapprehended the significance of the evidence Plaintiffs seek. Plaintiffs do not seek to show that these defendants *attempted* to make unilateral changes to their labels, rather Plaintiffs seek to show that the ANDA Defendants in fact made such changes, and *that they were permitted to do so by the FDA*. This evidence is especially important in light of the Court's reliance, in the Order, on the FDA's interpretation of its regulations. Evidence that the FDA, in fact, interprets these

[2] Plaintiffs believe that this evidence can be obtained primarily, if not exclusively, from the ANDA Defendants, whose files in all likelihood reflect the full course of their dealings with FDA with respect to these changes.

regulations to permit ANDA-holders to use the CBE regulations to make unilateral changes to labels for RLDs would surely be relevant to the Court's determination of whether ANDA-holders are permitted to do this, and thus whether they can comply with state-law warning duties without violating their federal regulatory duties. If, as this Court found, the question is how FDA understands and interprets the CBE regulations, evidence of how FDA interpreted them and acted on them in the past with respect to one of the specific drugs at issue here is surely relevant, especially in the absence of any statement or guidance from the FDA directly on point.

As noted above, this is all the more true because, after making successful, unilateral changes in 1991 and 1996, the Pfizer Defendants, at least, would have been aware that such changes were permitted even though Depo-Testosterone was approved pursuant to an ANDA. In this regard, Plaintiffs note that the 1996 change is especially significant, for if the FDA had informed the Pfizer Defendants in 1991 that the CBE regulations were not the proper avenue for label changes for this drug and that prior FDA approval for all such changes was required because Depo-Testosterone had been approved pursuant to an ANDA, it is unlikely that the Pfizer Defendants would have proceeded with the second unilateral change in 1996; they would have submitted their changes under the portion of the regulations requiring prior approval if they had been told that such prior approval was necessary. Indeed, had they proceeded with a second unilateral change after being told the first time that this kind of change was inappropriate, the FDA would in all likelihood have admonished them *not* to make unilateral changes in the future.

Plaintiffs respectfully suggest that evidence of how the FDA handled the ANDA Defendants' prior unilateral label changes to their RLD is the best means of determining whether ANDA-holders for RLDs are permitted to make such unilateral changes. The Court found that whether the ANDA Defendants are permitted to make unilateral changes to their labels is a legal question. Although Plaintiffs agree there is an underlying

legal question, it is also true that the regulations on this point are less than completely clear; in this context, evidence of the FDA's actual course of conduct when confronted when the precise type of change Plaintiffs contend the ANDA Defendants are permitted to make is surely relevant to understanding what the FDA believes the regulations mean and thus, in light of the Court's deference to the FDA, determining what the law is. For this reason, Plaintiffs respectfully request that the Court reconsider its decision to deny Plaintiffs the discovery they seek and that, upon reconsideration, the Court grant Plaintiffs' request for discovery, defer ruling on the ANDA Defendants' motion to dismiss, and permit Plaintiffs to present to the Court such evidence as they obtain in discovery demonstrating the meaning of the regulations at issue as determined by the FDA prior the Court's ruling on the motion to dismiss.

II. THE COURT SHOULD CLARIFY THE SCOPE OF ITS ORDER

The Court should also clarify the scope of its Order. Although the Order states that the motion to dismiss is granted "with regard to all claims involving defendants' drugs that were approved pursuant to abbreviated new drug applications," *see* Order at 15, the Order contains no discussion of how or why fraud-based claims arising from misrepresentations not contained in the labels for the Defendants' products would be preempted.

The basis of the Court's preemption ruling is the finding that "the ANDA defendants are prohibited from unilaterally altering their warning labels under federal law." Order at 14. The Court held that, as a result, the ANDA Defendants were precluded by federal law from changing their labels to conform to state-law standards concerning the adequacy of warnings. *Id.* Although Plaintiffs respectfully disagree with this ruling, even assuming it is correct, this rationale would have no applicability to claims that do not arise from the warning labels, but pertain rather to misrepresentations contained in advertising. The ANDA Defendants have never contended, nor could they,

that they were precluded from changing their advertising, at least not insofar as the requisite changes involve the removal of representations not also found in the product labels.

In connection with their Seventh Claim for Relief, sounding in fraud, Plaintiffs allege:

> Through a sophisticated and well-orchestrated marketing campaign, Defendants set out to invent a fictitious disease/medical condition that they called "Low T," and then purposely deceived Plaintiffs and their physicians into believing that this was a real disease/medical condition and that Plaintiffs suffered from it.

Third Amended Master Complaint ¶ 542. Plaintiffs further allege that "Defendants conducted sales and marketing campaigns to promote the sale of TRT products and willfully deceived Plaintiffs, Plaintiffs' physicians and the general public as to the benefits, health risks and consequences of using TRT products." *Id.* at ¶ 545. They allege that this sales and marketing campaign was carried out with "the intent: (a) to deceive physicians into prescribing TRT products for 'off-label' indications. . . ." *Id.* at ¶ 546. Plaintiffs also allege that this fraud was carried out "via patient-directed questionnaires, quizzes, and information, as part of mass marketing efforts to encourage patients to seek treatment for 'Low T'. . . ." *Id.* at ¶ 550. Plaintiffs further describe Defendants' "multi-platform marketing, promotional, educational, and awareness campaigns concerning the TRT products," *see* Third Amended Master Complaint at ¶ 551, and allege that Defendants' misrepresentations were conveyed "through their national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs," *id.* at ¶ 558.

Not one of these allegations pertains to statements in the FDA-approved labels for Defendants' TRT products. Indeed, because these allegations pertain to off-label marketing, *see* Third Amended Master Complaint ¶ 546, the representations at issue, by definition, *do not appear in the FDA-approved label*. For this reason, none of the regulatory

restrictions on unilateral changes to product labels that formed the basis of the ANDA Defendants' preemption applies. What Plaintiffs contend the ANDA Defendants ought to have done – removed their false and misleading statements from their multi-platform marketing campaign – does not conflict in any way with their federal law duties to maintain the FDA-approved label for their products. Nor, indeed, have the ANDA Defendants identified any conflict between their federal law duties and the state-law duties implicated in Plaintiffs' fraud-based claims arising from affirmative misrepresentations outside the product label.

The ANDA Defendants claimed, in their briefing, all of Plaintiffs' claims would have required them to change their product labels or to cease marketing their products, but this is manifestly not the case with respect to the Seventh Claim, sounding in fraud, nor indeed with respect to the Ninth and Tenth Claims (consumer protection and unjust enrichment, respectively), to the extent that those claims are based on affirmative misrepresentations outside the labels for the ANDA Defendants' TRT products. Because these claims are unrelated to the statements in the product label, and arise solely from statements outside the labels, the conflict between state and federal law identified by the Court as the basis for its preemption ruling does not exist here. (The Eleventh, Twelfth, Thirteenth and Fourteenth Claims are derivative of the other claims and thus to the extent that any of the substantive claims are not preempted, these claims, where applicable, would also not be preempted.)

Nor did the Court identify any other basis for finding Plaintiffs' claims preempted. Plaintiffs' respectfully suggest that, in the parties' focus on the legal issue as to whether the manufacturer of a product that, while approved through an ANDA, is also an RLD can avail itself of the unilateral label changes authorized by the Changes Being Effected regulations, there was a lack of clarity and precision about the scope of the arguments being made. This lack of clarity on the part of the parties carried over into the Order, which purports to dismiss all claims, but contains no rationale for dismissing claims that

do not pertain to the product labels, but rather only to misrepresentations made outside the labels (and not also found in the labels themselves). For this reason, Plaintiffs respectfully request that the Court clarify the scope of its Order, to explain whether the Court intended the Order to dismiss all claims, including the claims that do not arise from statements or omissions in the label, and if that was the Court's intention, the basis for that specific ruling.

CONCLUSION

For the foregoing reasons, the PSC respectfully requests the Court reconsider its November 9, 2015 Order and permit Plaintiffs to take discovery with respect to whether the FDA actually permitted unilateral CBE amendments to the labels in question before the Court rules on the ANDA Defendants' Motion to Dismiss. The PSC also respectfully requests that the Court clarify whether its Order applies to the fraud claim asserted in the Seventh Claim for Relief and, if so, on what basis.

Dated: December 22, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2015, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Trent B. Miracle
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